

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES
PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-2738-
FLW-LHG**

MDL No. 2738

THIS DOCUMENT RELATES TO ALL CASES

**THE PLAINTIFF STEERING COMMITTEE'S MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION TO EXCLUDE THE OPINIONS OF
ROBERT KURMAN, M.D.**

TABLE OF CONTENTS

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iii

I. INTRODUCTION AND SUMMARY 1

II. LEGAL STANDARD 2

III. ARGUMENT 3

 A. Dr. Kurman Should be Precluded from Offering a General Causation
 Opinion or Opinions on Biological Plausibility Because they were Not Disclosed
 in His Report 3

 B. Dr. Kurman Lacks Adequate Foundation to Offer Opinions Regarding Cell
 Biology or Cancer Biology 4

 C. Dr. Kurman’s Opinions Regarding Talc and Ovarian Cancer are Unreliable
 because Dr. Kurman Failed to Identify any Acceptable Methodology 4

 D. Dr. Kurman Should Be Precluded from Testifying that there is “No
 Evidence” that Talc Causes Ovarian Cancer 13

 E. Dr. Kurman Should Be Precluded from Testifying that it is Not Biologically
 Plausible that Chronic Inflammation Causes Ovarian Cancer 15

 F. Dr. Kurman Formed His Causation Opinions Based on a Heightened
 Standard of Certainty that will Likely Confuse and Mislead Juries 17

 G. Dr. Kurman’s Criticism of Dr. Kane’s Opinions and Report Rely Largely
 on Impermissible *Ipse Dixit* Opinions and Should Therefore be Excluded 24

 1. Similarities Between Talc and Asbestos and Between HGSC and
 Mesothelioma 24

 2. Talc-Induced Chronic Inflammation as a Cause of Ovarian Cancer 27

 3. Detection of Talc in Ovarian Tissue 30

 4. Migration of Talc to the Ovaries 32

IV. CONCLUSION 39

TABLE OF AUTHORITIES

Cases

Amorgianos v. Nat’l R.R. Passenger Corp.,
303 F.3d 256 (2d Cir. 2002)14

Brown v. Burlington N. Santa Fe Ry. Co.,
765 F.3d 765 (7th Cir. 2014)14

Calhoun v. Yamaha Motor Corp., U.S.A.,
350 F.3d 316 (3d Cir. 2003)5

Daubert v. Merrell Dow Pharm., Inc.,
43 F.3d 1311 (9th Cir. 1995)6

Daubert v. Merrell Dow Pharm., Inc.,
509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993) passim

Elcock v. Kmart Corp.,
233 F.3d 734 (3d Cir. 2000)10

Elsayed Mukhtar v. California State Univ., Hayward,
299 F.3d 1053 (9th Cir. 2002)23

Gen. Elec. Co. v. Joiner,
522 U.S. 136, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997)16

Haller v. AstraZeneca Pharm. LP,
598 F. Supp. 2d 1271 (M.D. Fla. 2009)12

Horan v. Dilbet, Inc.,
No. CIV.A. 12-2273, 2015 WL 5054856 (D.N.J. Aug. 26, 2015)..... 24, 25

In re Paoli R.R. Yard PCB Litig.,
35 F.3d 717 (3d Cir. 1994) 24, 25

In re Seroquel Prod. Liab. Litig.,
No. 6:06-MD-1769-ORL-22D, 2009 WL 3806434 (M.D. Fla. June 18,
2009)10

In re TMI Litig.,
193 F.3d 613 (3d Cir. 1999)13

In re Zolof (Sertralinehydrochloride) Prod. Liab. Litig.,
176 F. Supp. 3d 483 (E.D. Pa. 2016).....19

In re Zolof,
26. F. Supp. 3d 46110

Lake Michigan Contractors, Inc. v. Manitowoc Co.,

225 F. Supp. 2d 791 (W.D. Mich. 2002).....	11
<i>Leake v. United States</i> ,	
843 F. Supp. 2d 554 (E.D. Pa. 2011).....	19
<i>Magistrini v. One Hour Martinizing Dry Cleaning</i> ,	
180 F. Supp. 2d 584 (D.N.J. 2002).....	10, 19
<i>Matrixx Initiatives, Inc. v. Siracusano</i> ,	
563 U.S. 27, 131 S. Ct. 1309, 179 L. Ed. 2d 398 (2011)	24
<i>McMunn v. Babcock & Wilcox Power Generation Grp., Inc.</i> ,	
No. CIV.A. 10-143, 2013 WL 3487560 (W.D. Pa. July 12, 2013).....	13
<i>Munoz v. Orr</i> ,	
200 F.3d 291 (5th Cir. 2000)	12
<i>Nye v. Mistick</i> ,	
No. 1:13-CV-1905, 2015 WL 11511580 (M.D. Pa. Feb. 24, 2015)	23, 25
<i>Oddi v. Ford Motor Co.</i> ,	
234 F.3d 136 (3d Cir. 2000)	6
<i>Padillas v. Stork-Gamco, Inc.</i> ,	
186 F.3d 412 (3d Cir. 1999)	1
<i>Perry v. United States</i> ,	
755 F.2d 888 (11th Cir. 1985)	10
<i>Player v. Motiva Enterprises, LLC</i> ,	
240 F. App'x 513 (3d Cir. 2007).....	6
<i>Rimbert v. Eli Lilly & Co.</i> ,	
No. CIV 06-0874 JCH/LFG, 2009 WL 2208570 (D.N.M. July 21, 2009) ...	14
<i>Schneider ex rel. Estate of Schneider v. Fried</i> ,	
320 F.3d 396 (3d Cir. 2003)	5
<i>Smelser v. Norfolk S. Ry. Co.</i> ,	
105 F.3d 299 (6th Cir. 1997)	11
<i>Smith v. Ryan</i> ,	
813 F.3d 1175 (9th Cir. 2016)	26
<i>Soldo v. Sandoz Pharm. Corp.</i> ,	
244 F. Supp. 2d 434 (W.D. Pa. 2003)	13
<i>Truck Ins. Exch. v. MagneTek, Inc.</i> ,	
360 F.3d 1206 (10th Cir. 2004)	14
<i>U.S. E.E.O.C. v. Rockwell Int'l Corp.</i> ,	
60 F. Supp. 2d 791, 797 (N.D. Ill. 1999).....	14
<i>United States v. Fleet Mgmt. Ltd.</i> ,	
No. CRIM.A. 07-279, 2008 WL 1924250 (E.D. Pa. Apr. 29, 2008)	12

Rules

Fed. R. Civ. P. 26(a) (2) (B) (i)-(ii)3

Fed. R. Evid. 104 (a)1

Fed. R. Evid. 4031

Fed. R. Evid. 7021

Fed. R. Evid. 7031

The Plaintiffs' Steering Committee ("PSC") respectfully submits this motion, pursuant to Fed. R. Evid. 104 (a), 702, 703 and 403, to preclude or limit the testimony of the Johnson & Johnson Defendants ("J&J") pathology expert, Robert Kurman, M.D.

I. INTRODUCTION AND SUMMARY

The burden is on J&J to demonstrate that Dr. Kurman has used a reliable scientific method to reach his opinions. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999). J&J has failed to meet its burden under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). The PSC agrees that Dr. Kurman is qualified as a pathologist to offer appropriate expert opinions that "fit" his actual expertise and the facts, if those opinions are the result of his use of a reliable methodology. However, Dr. Kurman's opinions do not meet the *Daubert* standards.

Dr. Kurman's expert Report is 24 pages long.¹ The first 11 pages contain no opinions about talc and ovarian cancer. Rather, the first half of the Report merely offers Dr. Kurman's personal background information and a general discussion of epithelial ovarian cancer and its histological subtypes.² The other half of his Report,

¹ See February 25, 2019 Expert Report of Robert Kurman, M.D. ("Kurman Report") attached hereto as **Exhibit A**.

² *Id.* at 1-12.

entitled “Dr. Sarah Kane’s Expert Report,” is a critique of Dr. Kane’s opinions. Dr. Kurman offers no causation opinions of his own (other than just stating that Dr. Kane’s causation opinions are wrong), and he describes no methodology. Because there are no articulated causation opinions within Dr. Kurman’s Report, he should not be allowed to offer them at any trial.

Dr. Kurman’s causation opinions (offered only at his deposition and not in his Report) also are completely devoid of any acceptable methodology other than *ipse dixit*. Dr. Kurman’s opinions also are not based on his consideration of the totality of the evidence and were formed using a heightened and inappropriate standard of certainty, which will not be helpful to, and will likely mislead and confuse a jury. As such, none of Dr. Kurman’s opinions regarding talc and ovarian cancer will assist the trier of fact, and they should be excluded.

II. LEGAL STANDARD

The PSC incorporates the legal standard in its Omnibus Brief Regarding *Daubert* Legal Standard and Scientific Principles for Assessing General Causation (“*Omnibus Brief*”) as if set forth in entirety as supplemented herein.

III. ARGUMENT

A. Dr. Kurman Should be Precluded from Offering a General Causation Opinion or Opinions on Biological Plausibility Because they were Not Disclosed in His Report

Fed. R. Civ. P. 26(a) (2) (B) (i)-(ii) sets forth the requirements of an expert report. Expert reports “must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; and (ii) the facts or data considered by the witness in forming them.” (Emphasis added).

A review of Dr. Kurman’s Report reveals that his focus only was to criticize several opinions of the PSC’s expert pathologist, Dr. Sarah Kane. Dr. Kurman’s Report does not offer any general causation opinion, it does not offer an opinion on biological plausibility, it does not identify Dr. Kurman’s methodology, it does not explain how he weighed the scientific evidence and it only rarely provided the basis for his opinions. Therefore, since Dr. Kurman’s Report does not meet the requirements of Fed. R. Civ. P. 26 (a) (2) (B) (i)-(ii) because it does not disclose general causation and biological plausibility opinions or the basis for them, he should not be permitted to testify about those opinions.

B. Dr. Kurman Lacks Adequate Foundation to Offer Opinions Regarding Cell Biology or Cancer Biology

By Dr. Kurman's own admission, he is not an expert in cancer biology and did not intend to offer opinions in cancer biology.³ Further, he has never conducted a single study to observe the effects of talc on gynecologic tissue (or any tissue for that matter),⁴ nor has he even read the available cell studies observing talc's effect on cells.⁵ The fact is, Dr. Kurman did not even review the available cellular biology data in forming his opinions about talc and ovarian cancer.⁶

C. Dr. Kurman's Opinions Regarding Talc and Ovarian Cancer are Unreliable because Dr. Kurman Failed to Identify any Acceptable Methodology

As detailed in the PSC's *Omnibus Brief*, the second part of the Third Circuit's three-prong test of admissibility of expert testimony requires an expert's testimony to be reliable: "the expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation...."⁷ Dr. Kurman's loose methodology satisfies *none* of these reliability considerations.

³ See April 2, 2019 Deposition of Robert Kurman, MD ("Kurman Dep.") at 35:12-17, attached hereto as **Exhibit B**.

⁴ *Id.* at 23:10-16 and 26:10-16.

⁵ *Id.* at 19:9-18.

⁶ *Id.* at 29:13-30:12.

⁷ *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) ("...the testimony must be reliable.... 'the expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported

When asked what methodology he employed in formulating his opinions about whether talc could cause ovarian cancer, Dr. Kurman described an *ipse dixit* method:

Q. What methodology do you use to reach conclusions about biologic plausibility?

A. Well, to begin with, as I said early on in the deposition, I have spent 40 years looking at gynecologic pathology, which ovarian cancer is one of those. I have read extensively and kept up with the literature. I've edited the third, fourth, fifth, sixth, and in the process of the seventh edition, of Blaustein's pathology textbook. I was the lead author on the 2014 WHO classification of ovarian cancer. I participate in meetings, both domestically and internationally. I review papers, as we discussed earlier. So I think all of that together amounts to the way I evaluate biological plausibility.

Q. Is that a complete description of your methodology used to evaluate biologic plausibility?

A. Well, as I mentioned also, in this particular case, I reviewed what Dr. Kane claimed or alleged that were causative agents. I review those papers specifically. So that in addition to everything else I described.⁸

Dr. Kurman's opinions are nothing more than *ipse dixit* -- dogmatic, unproven assertions with no evidentiary support or foundation.⁹

speculation...") (citations omitted). *See also Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003).

⁸ Exhibit B, Kurman Dep. at 65:8-66:5.

⁹ *See Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315–16 (9th Cir. 1995) (“[S]omething doesn't become ‘scientific knowledge’ just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were ‘derived

Q. So your methodology for evaluating biologic plausibility is your reliance on your experience, your review of the literature, your publication literature, ... your review of other expert opinions on it?....Did I leave anything out?

A. I think that pretty much covers it.¹⁰

Dr. Kurman's opinions are based *primarily* on his "experience." Dr. Kurman has failed to read and consider many of the major peer-reviewed studies on talc and ovarian cancer. Dr. Kurman admitted that his reference lists appended to his Report omit "quite a few" epidemiology studies, and do not even include all the epidemiology and meta-analysis studies on talc and ovarian cancer.¹¹ Dr. Kurman also conceded that he did not read a number of seminal studies involving talc and ovarian cancer, including the Terry pooled-analysis, Taher's meta-analysis, Penninkalampi's meta-analysis (he read only the abstract), the Fletcher cell study, the McDonald lymph node study, the Health Canada Screening Assessment Report on talc and ovarian cancer, and the Ness meta-analysis.¹²

Some of the critical studies ignored by Dr. Kurman include:

by the scientific method' be deemed conclusive...."); *Oddi v. Ford Motor Co.*, 234 F.3d 136, 158 (3d Cir. 2000); *Player v. Motiva Enterprises, LLC*, 240 F. App'x 513, 520 (3d Cir. 2007) (the "District Court certainly had the discretion to exclude opinion evidence that is connected to existing data only by the ipse dixit of the expert." (internal citations omitted)).

¹⁰ Exhibit B, Kurman Dep. at 66:6-14.

¹¹ *Id.* at 41:17-21, and 43:6-9.

¹² *Id.* at 33:11-12; 33:22-24; 190:20-191:3; 270:2-8; 320:24-321:25.

- ✓ Terry, et al. (2013)¹³ – Pooled analysis of 8 case-control studies of 18,384 woman. Found genital talc use increases woman’s risk of ovarian cancer by 24-46%.
- ✓ Penninkilampi, et al. (2018)¹⁴ – A meta-analysis of 29 studies, including 33,625 women. “[T]he confirmation of an association in cohort studies between perineal talc use and serous invasive ovarian cancer is suggestive of a causal association.” “There is a consistent association between perineal talc use and ovarian cancer.”
- ✓ Schildkraut, et al. (2016)¹⁵ “In this study of African-American women, body powder use was significantly associated with epithelial ovarian cancer risk.”
- ✓ Ness, et al. (2015)¹⁶ – meta-analysis of 31 talc studies. Perineal talc use increased risk of ovarian cancer by 30-60%. Bradford Hill analysis supports causal association between talc use and ovarian cancer.
- ✓ Taher, et al.¹⁷ - A Meta-analysis of 30 studies “for qualitative assessment of evidence” found a “positive association

¹³ **Exhibit C**, “Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls,” Terry, et al. (Cancer Prevention Research, 2013).

¹⁴ **Exhibit D**, “Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis,” Penninkilampi and Eslick (*Epidemiology*, 2018).

¹⁵ **Exhibit E**, “Association Between Body Powder Use and Ovarian Cancer: The African-American Cancer Epidemiology Study,” Schildkraut, et al. (American Journal for Cancer Research, 2016).

¹⁶ **Exhibit F**, “Does Talc Exposure Cause Ovarian Cancer?” Ness, et al. (International Journal of Gynecological Cancer: Official Journal of the International Gynecological Cancer Society, 2015).

¹⁷ **Exhibit G**, “Systematic Review and Meta-analysis of the Association Between Perineal Use of Talc and Risk of Ovarian Cancer,” Taher, et al. (publication pending, accepted by Health Canada for its aforementioned review, 2018).

between perineal use of talc powder and ovarian cancer” reflecting an overall increase risk to genital talc users of 28%.

- ✓ McDonald, et al.¹⁸ – A tissue study of talc in pelvic lymph nodes of genital talc users. Found both platy and fibrous talc particles in pelvic lymph nodes draining from female reproductive tract. “This study supports earlier observations that talc particles, from perineal exposure, can and do migrate to pelvic lymph nodes.” (p. 12) “Exposure (such as perineal application), whether known clinically or not, often results in significant deposition of talc in the tissues.” (p.14)
- ✓ Fletcher, et al.¹⁹ – A study of cells exposed to talc. “Remarkably, talc exposure induced specific mutations that are known to alter the activity in ...key enzymes. Talc exposure also resulted in a significant increase in inflammation as determined by increased tumor marker CA-125 ($P < .05$). More importantly, talc exposure significantly induced cell proliferation and decreased apoptosis in cancer cells and to a greater degree in normal cells ($P < .05$).” Findings “confirm the cellular effect of talc and provide a molecular mechanism to previous reports linking genital use to increased ovarian cancer risk.” (p.1).
- ✓ Health Canada Review – A comprehensive review of health risks associated with genital talc use, particularly the risk of ovarian cancer “[A]vailable data are indicative of a causal effect.” (**Exhibit J**, Draft Screening Assessment, Talc, Environment and Climate Change Canada, Health Canada, December 2018, p.iii)

¹⁸ **Exhibit H**, "Correlative Polarizing Light and Scanning Electron Microscopy for the Assessment of Talc in Pelvic Region Lymph Nodes," McDonald, et al. (*Ultrastructural Pathology*, 2019).

¹⁹ **Exhibit I**, “Molecular Basis Supporting the Association of Talcum Powder Use With Increased Risk of Ovarian Cancer,” Fletcher, et al. (*Reproductive Sciences*, 2019).

This is not an exhaustive list of critical studies Dr. Kurman never read, but it is enough to demonstrate he has not followed a reliable methodology that assesses all of the pertinent scientific evidence, and that he cherry-picked the literature to support his opinions, making it obvious that Dr. Kurman's testimony regarding talc and ovarian cancer is litigation-derived. He did not prepare the supplemental reference list provided to the PSC the day before his deposition, *nor had he even seen it. And he did not read most of the studies and reports identified therein.*²⁰ “[T]he reliability of an expert's opinion should be seriously questioned when it is shown that the expert formed his or her opinion prior to reviewing scientific evidence, and, thereafter, merely cherry-picked evidence favorable to that opinion.”²¹ The Third Circuit deems expert opinions unreliable where the expert ignores material evidence when formulating his or her opinions.²²

²⁰ Exhibit B, Kurman Dep. at 12:11-14:7.

²¹ *In re Seroquel Prod. Liab. Litig.*, No. 6:06-MD-1769-ORL-22D, 2009 WL 3806434, at *5 (M.D. Fla. June 18, 2009) (“A scientist who has a formed opinion as to the answer he is going to find before he even begins his research may be less objective than he needs to be in order to produce reliable scientific results.” (citing *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985))); *In re Zolof*, 26. F. Supp. 3d 461.

²² *See Elcock v. Kmart Corp.*, 233 F.3d 734, 756 (3d Cir. 2000); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602 (D.N.J. 2002) (“in order for an expert's opinions based on evidence to be reliable and admissible, “all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science.”)

That Dr. Kurman's opinions are litigation-driven is evidenced further by the fact that his opinions on key issues since becoming a J&J expert directly contradict statements in his own textbook (*Blaustein's Pathology of the Female Genital Tract*, 6th ed. 2011) that predate his retention by J&J. For example, in his deposition, Dr. Kurman opined that retrograde menstruation does not introduce foreign materials like talc or other potential environmental carcinogens into the uterus and fallopian tubes.²³ Yet, Chapter 14 of his *Blaustein's* 6th ed., states "In addition, hysterectomy and tubal ligation prevent the introduction of a variety of potential environmental carcinogens from entering the peritoneal cavity and thereby coming into contact with tubal and ovarian tissue."²⁴

Similarly, his textbook (*Blaustein's* 6th ed.) states that inflammation and surface damage of the ovary can be attributable to the introduction of foreign material through the vagina and uterine cavity, playing an important role in ovarian carcinogenesis,²⁵ and that this mechanistic explanation "reflects the general consensus of what's out there." *Id.* at 163:2-8. Yet, Dr. Kurman now testifies for J&J that foreign materials *cannot* migrate from the vagina to the ovaries.²⁶ The numerous

²³ Exhibit B, Kurman Dep. at 123:21-125:14.

²⁴ *Id.* at 127:25-128:5.

²⁵ *Id.* at 159:22-160:14

²⁶ *Id.* at 275:11-16.

inconsistencies between Dr. Kurman's present testimony for J&J, and his unequivocal statements made in his *Blaustein's* textbooks show that his present testimony is contrived, unsupported, and litigation driven.²⁷

Interestingly, Dr. Kurman acknowledged in his deposition that, in order to reach conclusions about causation (*i.e.* with a proper methodology), an expert must consider the Bradford Hill causal association analysis.²⁸ In fact, when asked, "What do you need to see between the foreign-body response that you're describing and the cancer to link the two?"²⁹ Dr. Kurman responded:

I'd like to see fulfillment of the various criteria that we talked about before, Bradford Hill, to really say that all the various studies, not

²⁷ See *Smelser v. Norfolk S. Ry. Co.*, 105 F.3d 299, 303 (6th Cir. 1997) (stressing that the court should consider litigation motivation in assessing the reliability of the expert opinion); *Lake Michigan Contractors, Inc. v. Manitowoc Co.*, 225 F. Supp. 2d 791, 803 (W.D. Mich. 2002) (An expert who "starts with his conclusion ... and then works backward for reasons to explain this conclusion without focusing on the specific facts and circumstances of the case" does not display the reliability that Daubert demands); *Munoz v. Orr*, 200 F.3d 291, 301 (5th Cir. 2000) (affirming exclusion of expert who "began his analysis with the assumption [plaintiff sought to prove]" and holding that this was "an indicator that he lacked the necessary objectivity to make his analyses credible"); *United States v. Fleet Mgmt. Ltd.*, No. CRIM.A. 07-279, 2008 WL 1924250, at *6 (E.D. Pa. Apr. 29, 2008) (excluding purported industry expert whose opinions were formulated "as an outgrowth of his role as one of the Government's primary fact witnesses at trial" where expert "approached his investigation with a particular conclusion in mind ... and, without using any clearly-defined methodology, much less any intellectually rigorous analysis, he concluded that select facts and data could be interpreted to support that conclusion"); *Haller v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1271, 1297 (M.D. Fla. 2009).

²⁸ Exhibit B, Kurman Dep. at 47:9-17.

²⁹ *Id.* at 100:14-101:4.

just biologic plausibility but strength of association from epidemiologic studies, dose response, consistency, the various factors that Bradford Hill requires to show causality. That's what I want to see, and I haven't seen it.³⁰

A problem with Dr. Kurman's opinions regarding talc and ovarian cancer is that he did not perform the very analysis that he said was required. The Third Circuit has held that where an expert acknowledges that a particular method is the "preferable methodology" to use for an analysis, but the expert does not use that methodology, his testimony should be excluded. *In re TMI Litig.*, 193 F.3d 613, 692 (3d Cir. 1999). In analyzing the reliability of an expert's opinion, "it is appropriate for the Court to consider whether the testimony [the expert] intends to give faithfully complies with *their own views* of what standards constitute the scientific method." *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 560 (W.D. Pa. 2003) (emphasis added). Courts routinely have excluded expert testimony where the expert has failed to use the very methodology that he or she normally uses outside of the courtroom.³¹

³⁰ *Id.* at 100:22-101:4.

³¹ See *McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, No. CIV.A. 10-143, 2013 WL 3487560, at *22 (W.D. Pa. July 12, 2013) ((expert's failure to apply the Bradford Hill criteria, which he has called the "gold standard" in this field, when he ordinarily does so is significant) citing *Rimbert v. Eli Lilly & Co.*, No. CIV 06-0874 JCH/LFG, 2009 WL 2208570, at *14 (D.N.M. July 21, 2009) ("That Dr. Jackson chose not to apply the methodology that she personally considers to be the standard in her field to assess causation [Bradford Hill criteria] undermines the reliability of her testimony."); *Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 773, 776 (7th Cir. 2014) (affirming exclusion of expert testimony where expert failed to follow his own description of proper methodology); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268–69 (2d Cir. 2002) (affirming exclusion of

**D. Dr. Kurman Should Be Precluded from Testifying that there is
“No Evidence” that Talc Causes Ovarian Cancer**

Dr. Kurman testified that although inflammation may play a role in causing other tumors, “there's absolutely no evidence” that inflammation causes ovarian cancer.³² Dr. Kurman’s reason - “I don’t think it [talc] causes cancer is because there’s been absolutely **no evidence** in the literature that it does.”³³ This general causation opinion (and all variations of it) should be excluded for the following reasons: (1) Dr. Kurman did not provide a general causation opinion in his Report; (2) Dr. Kurman did not set forth the basis for a general causation opinion in his Report; (3) Dr. Kurman did not describe his general causation methodology in his Report; (4) Dr. Kurman’s Report did not describe how he weighed the general causation evidence; (5) any claim by an expert witness that there is “no evidence” is definitionally based on an unreliable methodology, unless the expert has considered all of the evidence, and explained why the evidence cited by other experts should be

expert where expert failed to reliably apply his own methodology); *Truck Ins. Exch. v. MagneTek, Inc.*, 360 F.3d 1206, 1213 (10th Cir. 2004) (“The district court noted that [the expert]’s opinion did not meet the standards of fire investigation [the expert] himself professed he adhered to.”); *U.S. E.E.O.C. v. Rockwell Int’l Corp.*, 60 F. Supp. 2d 791, 797 (N.D. Ill. 1999) (same).

³² Exhibit B, Kurman Dep., at 62:1-5.

³³ *Id.* at 183: 4-7. (Emphasis added).

dismissed or disregarded, and Dr. Kurman admitted that he has not done so;³⁴ (6) Dr. Kurman employed an inappropriate standard of certainty for assessing the causation evidence (discussed *infra*); and (7) Dr. Kurman's opinion is based only on *ipse dixit*.

To legitimately claim that there is "no evidence" to support a proposition, naturally one must first at least consider the evidence on which the PSC's experts rely in reaching their opinion that there in fact is substantial evidence that talc exposure causes ovarian cancer. Based on Dr. Kurman's list of materials considered, it is clear that he did not review a substantial amount of the evidence relied upon by the PSC's experts. (discussed *supra*.)

There is *substantial* evidence that talc causes ovarian cancer. That evidence is discussed in the reports of the PSC's expert witnesses. Dr. Kurman did not review

³⁴ As detailed above, Dr. Kurman testified that he did not even read any of the plaintiffs' expert reports except for the report of Dr. Kane (which has over 170 medical literature references, and which Dr. Kane cited to support her general causation opinion). Dr. Kurman's proclamation of "no evidence" could only be reliable if he actually considered the evidence cited by plaintiffs' experts, and if he explained why those references do not constitute evidence of general causation. Without reading the other expert reports and without explaining why medical literature evidence relied on by each plaintiff's expert and by Dr. Kane does not support causation, Dr. Kurman could not reliably conclude that there is "no evidence." He did not explain or even address the vast medical literature relied on by Dr. Kane. Accordingly, as it stands, Dr. Kurman's "no evidence" statement is nothing more than *ipse dixit*.

any of those reports except for Dr. Kane's Report.³⁵ Even a cursory review of those reports reveals that there is substantial medical and scientific evidence supporting a general causation opinion. Accordingly, Dr. Kurman's opinion that there is "no evidence" is not based on a reliable methodology and also does not "fit" the facts.³⁶

Dr. Kurman could have undertaken to evaluate and interpret and apply the medical evidence relied on by the PSC's experts before reaching his "no evidence" opinion. He could have disagreed with the PSC's experts' interpretations and assessments of the published studies and the text books and medical articles on which they relied. He did not do any of that. The scientific evidence relied on by the PSC's experts were largely ignored by Dr. Kurman.

E. Dr. Kurman Should Be Precluded from Testifying that it is Not Biologically Plausible that Chronic Inflammation Causes Ovarian Cancer

Dr. Kurman testified that it is not biologically plausible that the type of inflammation caused by talc can cause ovarian cancer.³⁷ The basis for this opinion

³⁵ Exhibit B, Kurman Dep., at 13:11-18.

³⁶ *Daubert*, 509 U.S. at 591 (explaining that expert testimony must "fit," or be relevant to, the facts of the case). There is too great an "analytical gap." See *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997) (holding that the trial court "may conclude that there is simply too great an analytical gap between the data and the opinion proffered").

³⁷ Exhibit B, Kurman Dep. at 62:14-63:3.

is that he has not seen it and has not seen it described in the medical literature.³⁸ This amounts to an opinion based only on the *ipse dixit* of Dr. Kurman and should be excluded on that basis.

Dr. Kurman additionally offers the opinion that it is not biologically plausible that any type of chronic inflammation causes ovarian cancer, because he has “seen **no evidence** of chronic inflammation causing ovarian cancer,”³⁹ and because he has not read about it.⁴⁰ This opinion should be excluded because (1) Dr. Kurman did not provide a biological plausibility opinion in his Report; (2) Dr. Kurman’s Report did not set forth the basis for this biological plausibility opinion; (3) Dr. Kurman’s Report did not describe his methodology for assessing biological plausibility; (4) Dr. Kurman’s Report did not describe how he weighed the evidence pertaining to biological plausibility; (5) any claim by an expert witness that there is “no evidence” is by definition based on an unreliable methodology, unless the expert has considered all of the evidence, and explained why the evidence cited by other experts should be disregarded, and Dr. Kurman has admittedly not done so; (6) Dr. Kurman employed an inappropriate standard of certainty for assessing biological plausibility; and (7) Dr. Kurman’s biological plausibility opinion is based only on *ipse dixit*.

³⁸ *Id.*

³⁹ *Id.* at 64:22-23. (Emphasis added)

⁴⁰ *Id.* at 64:24-65:6.

F. Dr. Kurman Formed His Causation Opinions Based on a Heightened Standard of Certainty that will Likely Confuse and Mislead Juries

Dr. Kurman's causation and biological plausibility opinions also should be excluded because Dr. Kurman formed those opinions based on the application and utilization of an incorrect standard of certainty to assess all causation questions. Throughout his deposition, Dr. Kurman testified about a standard that he used in forming his opinions; one that is much higher than the preponderance of evidence standard applicable to this case. Although Dr. Kurman gave lip service to the preponderance of the evidence standard (only after being asked three times and in response to a suggestive question), it is evident that he has not followed that standard in this case. Rather, Dr. Kurman's standard can be summarized as one where if he has not seen it, it cannot be, and therefore, "I'm not convinced."

For example, when asked whether it would constitute evidence that talc exposure could cause ovarian cancer if talc elicited a particular mutation response (a p53 mutation), Dr. Kurman testified that it would not be evidence of causation because "having a p53 mutation, in and of itself, *does not inevitably mean a tissue is going to become malignant.*"⁴¹

⁴¹ *Id.* at 182:6-183:7. (Emphasis added). Most TP53 mutations change single amino acids in the p53 protein, which leads to the production of an altered version of the protein that cannot control cell proliferation and is unable to trigger apoptosis (cell death) in cells with mutated or damaged DNA. As a result, DNA damage can accumulate in cells. There is evidence that talc affects p53 expression. As just one

The definition of general causation is whether exposure to talc *is capable of* causing ovarian cancer.⁴² Dr. Kurman’s heightened “**not inevitably**” standard is not compatible with the civil law preponderance of evidence standard or with the definition of general causation.

This was not an isolated statement. Dr. Kurman repeatedly revealed the improper standard he was using. When asked if a p53 mutation response would not be suggestive that the tissue might become malignant, Dr. Kurman dug in, and testified “**not necessarily**...you can have a p53 mutation and have a perfectly benign lesion.”⁴³ When asked whether cells with damaged DNA can become cancer cells, his response was “**not necessarily**.”⁴⁴ Dr. Kurman simply refused to even consider addressing the causation question on any basis other than absolute certainty. This type of expert testimony will be misleading to juries who will very likely be confused

of her bases supporting her causation opinion, Dr. Kane’s report states at p. 13 “The strongest association of talc and ovarian cancer is with invasive serous carcinomas, which commonly have p53 mutations, and TNF- α induced chromosomal mutations occur mostly in cells with p53 aberrations. Talc has been shown to induce macrophage TNF- α expression, which has been shown to promote ovarian tumorigenesis.” (Dr. Kane’s citations omitted).

⁴² *Magistrini*, 180 F. Supp. 2d at 590; *see In re Zolof (Sertralinehydrochloride) Prod. Liab. Litig.*, 176 F. Supp. 3d 483, 491 (E.D. Pa. 2016); *see also Leake v. United States*, 843 F. Supp. 2d 554, 558 (E.D. Pa. 2011) Restatement (Third) of Torts: Liability for Physical and Emotional Harm [hereinafter Restatement] § 28 cmt. c(3) (2010)) (emphasis added).

⁴³ Exhibit B, Kurman Dep. at 182:5-21. (Emphasis added).

⁴⁴ *Id.* at 87:5-9. (Emphasis added).

by an expert whose frame of reference is to reject the preponderance of evidence standard while at the same time giving lip service to it. The following exchange makes this concern crystal clear:

Q. I'm not saying it necessarily would become cancer, but if talc can evoke a p53 response in tubal cells or ovarian cells, would that be evidence to you that talc could cause cancer?

THE WITNESS: No.

Q. Why did you say no?

THE WITNESS: Because, as I said, having a p53 mutation, in and of itself, does not inevitably mean a tissue is going to become malignant.

Q. Is it suggestive that a tissue might become malignant?

THE WITNESS: Not necessarily.

Q. What does that mean, "not necessarily"?

A. As I said, you can have a p53 mutation and have a perfectly benign lesion.⁴⁵

Dr. Kurman's responses make it clear that he was not only using the wrong standard for assessing causation and biological plausibility, he also was using a definition of biological plausibility that conflates "plausibility" with proof of mechanism and proof of causation with direct evidence. For example,

✓ When asked if exposure of the ovaries to asbestos causes cancer, his response was "**I'm not convinced.**"⁴⁶

⁴⁵ *Id.* at 181:16-183:24.

⁴⁶ *Id.* at 96:14-17. (Emphasis added).

- ✓ When asked if it was biologically plausible, he responded: “to me, it has to be seen. And **I haven’t seen it yet.**”⁴⁷
- ✓ He added: “I’d like to see more studies to be **more convinced** that it might be biologically plausible. At this point, **I’m not convinced.**”⁴⁸
- ✓ He testified “[a]t this point, **I’m not convinced** that it’s biologically plausible to cause ovarian cancer. I want to see something that shows me evidence of that, and I don’t see it.”⁴⁹
- ✓ When asked if asbestos could cause peritoneal malignancies, Dr. Kurman responded that it was “controversial...**not clear.**”⁵⁰
- ✓ He viewed the question as calling for a “**definitive** comment.”⁵¹
- ✓ Dr. Kurman was asked if he believed that talc could cause cancer in tubal cells, and he answered, “[N]ot necessarily.”⁵²
- ✓ Commenting on a published paper discussing how foreign materials may evoke a granulomatous reaction, Dr. Kurman’s response was that it was “**not definitive.**”⁵³ and,
- ✓ Regarding photos in a published paper showing talc found within tissue engulfed by macrophages, and whether this was evidence of talc exposure, Dr. Kurman was “**not convinced** [because]...they can all be wrong...they could be there as a contaminant, so **I’m not convinced.**”⁵⁴

⁴⁷ *Id.* at 96:18-23. (Emphasis added).

⁴⁸ *Id.* at 97:1-3. (Emphasis added).

⁴⁹ *Id.* at 97:19-22. (Emphasis added).

⁵⁰ *Id.* at 167:12-19. (Emphasis added).

⁵¹ *Id.* at 167: 12-24. (Emphasis added).

⁵² *Id.* at 180:14-18. (Emphasis added).

⁵³ *Id.* at 184:20. (Emphasis added).

⁵⁴ *Id.* at 198:9-199:1. (Emphasis added).

Given his repeated and numerous “I’m not convinced” responses to various questions exploring his causation opinions (which, as noted above, were not disclosed in his Report) about whether X constituted evidence of Y, he was asked what burden (i.e., what standard) he was applying for his opinions (is in “if you’re not convinced then it isn’t so?”). His response: **“I can only say what I believe in...I am not convinced.”**⁵⁵ He was asked a second time: “Is that the standard that you’re using for causation, that you’re not convinced?” His response was non-responsive to the question about the standard of certainty. He testified that his standard was the fulfillment of all various causation criteria.⁵⁶ So, he was asked a third time, specifically whether his standard was that he had to be convinced or whether it was “a level of a preponderance of the evidence in court. Is it until Dr. Kurman is convinced or is it a preponderance of evidence....?” His response was, “a preponderance of evidence, of course,⁵⁷ But his answers to almost every causation question, as illustrated above, was that he was using and demanding a much higher and more onerous standard of certainty when he assessed the question of causation coupled with an *ipse dixit* standard.

⁵⁵ *Id.* at 201:19-25. (Emphasis added).

⁵⁶ *Id.* at 202: 2-10.

⁵⁷ *Id.* at 202:12-20.

An expert's opinion "can be both powerful and quite misleading because of the difficulty in evaluating it."⁵⁸ *Daubert* standards address concerns regarding experts' "improper imprimatur of authority" and its effect on juries.⁵⁹

Longstanding legal principles govern the standard of proof in a civil case. In the Third Circuit and elsewhere, plaintiffs must prove the elements of the claims by a preponderance of evidence. This holds true for evidence of causation, including expert testimony. Plaintiffs' burden is to prove causation based on a "more probable than not" standard.⁶⁰ "It would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science."⁶¹ As the U.S. Supreme Court has recognized, it is a fallacy that scientists insist on certainty in making judgments outside the courtroom. "[M]edical professionals and researchers do not limit the data they consider to the results of

⁵⁸ *Daubert*, 509 U.S. at 595 (internal quotations and citations omitted).

⁵⁹ *Nye v. Mistick*, No. 1:13-CV-1905, 2015 WL 11511580, at *5 (M.D. Pa. Feb. 24, 2015); *see also Elsayed Mukhtar v. California State Univ., Hayward*, 299 F.3d 1053, 1063–64 (9th Cir. 2002) (noting the need to maintain *Daubert* standards to restrain "the aura of authority experts often exude" leading juries to afford more weight to the expert's testimony).

⁶⁰ *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 780 (3d Cir. 1994).

⁶¹ *Daubert*, 509 U.S. at 590. *See also Horan v. Dilbet, Inc.*, No. CIV.A. 12-2273, 2015 WL 5054856, at *13 (D.N.J. Aug. 26, 2015) (noting the unreasonableness of subjecting scientific testimony to a certainty standard).

randomized clinical trials or to statistically significant evidence.”⁶² The Third Circuit is clear that “it would be unreasonable to conclude that the subject of scientific testimony must be ‘known’ to a ‘certainty.’”⁶³

Nor will such testimony “assist the trier of fact.” To the contrary, it will tend to obfuscate and confuse. Opinions that are based on the incorrect legal standard cannot be helpful to the jury and, in fact, create confusion. The very purpose of expert testimony is to help the jury understand the evidence or determine a fact in issue.⁶⁴ In its gate-keeper role, the court is tasked with balancing the admission of reliable, helpful expert testimony with the exclusion of that which is misleading or confusing.⁶⁵

Witness testimony couched in the phrase “I’m not convinced” and “not necessarily” is powerful and resonant. When uttered from the mouths of experts, this testimony poses a strong risk of misleading the jury to give it undue weight.⁶⁶

⁶² *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 40–42, 131 S. Ct. 1309, 179 L. Ed. 2d 398 (2011).

⁶³ *Horan*, 2015 WL 5054856, at *13 (citing *Daubert*, 509 U.S. at 590).

⁶⁴ Fed. R. Evid. 702 (a).

⁶⁵ See *Daubert*, 509 U.S. at 595; *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d at 746 (“[A]dmissibility of scientific testimony turns not only on reliability but also the possibility that admitting the evidence would overwhelm, confuse, or mislead the jury...in conducting this balancing inquiry, there is a presumption of helpfulness.”).

⁶⁶ See *Nye*, 2015 WL 11511580, at *5 (cautioning that experts that exude improper authority can lead juries to give their opinions more weight).

The “certainty” testimony is sure to confuse the jury during deliberation because it contradicts the jury instruction that plaintiffs must prove their claims by a preponderance of the evidence.⁶⁷ Dr. Kurman’s personal, subjective standard for weighing evidence should not be permitted, and the opinions based on those standards are unreliable and would certainly mislead a jury.

G. Dr. Kurman’s Criticism of Dr. Kane’s Opinions and Report Rely Largely on Impermissible *Ipsa Dixit* Opinions and Should Therefore be Excluded

Dr. Kurman’s criticism of Dr. Kane’s opinions in his Report should be excluded because they are based only on impermissible *ipse dixit*.

1. Similarities Between Talc and Asbestos and Between HGSC and Mesothelioma

Dr. Kurman’s criticisms of Dr. Kane’s opinion that there are striking similarities between talc and asbestos, and between HGSC (high grade serous carcinoma – the most common type of ovarian cancer) and mesothelioma should also be excluded primarily because Dr. Kurman readily admits “I’m not an expert on mesothelioma and asbestosis. However, I would agree that asbestos causes mesothelioma-- pleural mesothelioma and potentially these mechanisms might

⁶⁷ See *Smith v. Ryan*, 813 F.3d 1175, 1199 (9th Cir. 2016) (“If a trained psychiatrist has difficulty with the categorical ‘beyond a reasonable doubt’ standard, the untrained lay juror—or indeed even a trained judge—who is required to rely upon expert opinion could be forced by the criminal law standard of proof to reject commitment for many patients desperately in need of institutionalized psychiatric care.”).

explain it, but I haven't studied it.”⁶⁸ Secondly, his criticisms of Dr. Kane are mere *ipse dixit*. Dr. Kurman works to minimize the similarities between talc and asbestos to challenge Dr. Kane's analogy between the two. Relying only on *ipse dixit*, Dr. Kurman improperly opines that talc is inert (and asbestos is not), that occupationally-inhaled asbestos is not relevant to the perineal application of talcum powder, and that HGSC and mesothelioma were viewed at too high of a magnification instead of through “routine microscopic analysis.”⁶⁹

An important difference, in Dr. Kurman's opinion, is that “talc is inert” and thus does not mimic the pathogenic effects of asbestos.⁷⁰ This seems to be an opinion Dr. Kurman only holds some of the time, despite his citation to IARC. Dr. Kurman concedes “that talc can elicit an inflammatory response in tissue”⁷¹ If talc is inert, then an inflammatory response would not be expected. Dr. Kurman's willingness to contradict himself on this issue indicates that his opinion that “talc is inert” is transitory—it is only true when he says it is true. If Dr. Kurman cannot pick a

⁶⁸ Exhibit B, Kurman Dep. at 82:13-17. Dr. Kurman even disavows his asbestos expertise twice more: “Well, again, I'm not an expert on the different types of asbestos. I would leave--I would defer to a mineralogist to agree as to whether all types, as they state here, are associated with cancer.” *Id.* at 90:8-12; and “As I said earlier, when it comes to the specifics of the composition of asbestos or, for that matter, talc, I would defer to a mineralogist.” *Id.* at 91:15-17.

⁶⁹ Exhibit A, Kurman Report at 14.

⁷⁰ *Id.* at 13.

⁷¹ *Id.* at 15.

position based on a scientific methodology, the opinions he gives on this topic are tantamount to impermissible *ipse dixit*.

Similarly, Dr. Kurman criticizes the studies cited by Dr. Kane that involve asbestos exposure and ovarian cancer, stating that the occupationally-inhaled asbestos is not applicable to the perineal application of cosmetic talcum powder.⁷² Dr. Kurman describes differences between the substances without detailing why the similarities noted in Dr. Kane's report are not meaningful, and he does not explain how or why talc and asbestos are scientifically or medically incomparable. Dr. Kurman also describes "a significant likelihood" that the tumors in those studies were misclassified but fails to detail a methodology or basis for arriving at that conclusion. Dr. Kurman says that there is a "significant likelihood" only because he says so, which is the definition of *ipse dixit*.

Dr. Kurman dismisses Dr. Kane's observation about the visual similarities between talc-induced HGSC and asbestos-induced mesothelioma because he contends that the tumor photomicrographs were taken at too high a magnification, saying that "it is relatively straightforward for an experienced gynecologic pathologist to distinguish between HGSC and mesothelioma by morphology on routine microscopic analysis." *Id.* at 14. Dr. Kurman does not provide a description of the proper methodology for routine microscopic analysis. He does not give the

⁷² *Id.* at 14.

appropriate magnification to view images of HGSC and mesothelioma. He does not explain why the degree of magnification results in only the appearance of similarities. Dr. Kurman's opinions here lack the prerequisite scientific foundation and amount to *ipse dixit* opinions.

2. Talc-Induced Chronic Inflammation as a Cause of Ovarian Cancer

Dr. Kane's Report states that chronic inflammation is a biologically plausible mechanism for talc-induced ovarian cancer. For example, Dr. Kane states on page 4 of her Report, "Once reaching the ovaries, talcum powder products can cause chronic inflammation, can increase oxidative stress, and can reduce immune response. These are biologically plausible and likely mechanisms for ovarian cancer development and progression."⁷³ Dr. Kurman ignores the distinction between biological plausibility and proof of causation, and mischaracterizes Dr. Kane's opinions about inflammation, stating that it is her opinion that talc-induced chronic inflammation is a "cause" of ovarian cancer. After misstating her opinion, Dr. Kurman opines that granulomatous inflammation in ovarian tumors "had nothing to do with talc" in his experience, that the latency period between the onset of talc-related inflammation and the development of cancer cannot occur when the inflammation is continuous, and that the chronic inflammation associated with

⁷³ November 15, 2018 Expert Report of Sarah E. Kane, M.D. ("Kane Report") at 4, attached hereto as **Exhibit K**.

diseases like ulcerative colitis is irrelevant to the inflammation associated with a foreign body like talc.⁷⁴

Dr. Kurman critiques Dr. Kane's opinion that perineal talc causes chronic inflammation by stating that the granulomatous inflammation in ovarian tumors, in his experience, "had nothing to do with talc."⁷⁵ In support, Dr. Kurman cites only to his "40 years of looking at microscopic slides of ovarian cancer."⁷⁶ He relies on the polarization of those ovarian tumors to exclude talc as the cause of the observed inflammation.⁷⁷ Dr. Kurman does not provide the relevant data from his experience or any resulting medical literature, trusting only his memory to span four decades to recall each polarized tumor he examined. His recollection of the polarized tumors is also questionable given his own description of proper methodology: "polarization is not routinely employed by surgical pathologists."⁷⁸ Offering no data or medical literature support for his opinion, and with no description of his methodology other than 40 years' experience, Dr. Kurman's opinion that granulomatous inflammation in ovarian tumors have nothing to do with talc in his experience amounts to *ipse dixit*.

⁷⁴ Exhibit A, Kurman Report at 16, 18.

⁷⁵ *Id.* at 16.

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.* at 20.

Dr. Kurman next discounts the potential for a latency period between the onset of talc-related inflammation and the development of cancer without providing support in the literature and without describing his own methodology. He criticizes Dr. Kane's opinion about this latency period by speculating that "it appears that for most cases, the exposure and, therefore, the resulting inflammation, would not be remote but continuous."⁷⁹ Dr. Kurman offers no basis for this opinion that inflammation would be continuous, and the opinion is itself just based on his say-so. He implies without explanation, with no citation to medical literature, or scientific methodology that continuous inflammation would not allow for a latency period between the onset of inflammation and cancer development.⁸⁰ Without further scientific support, this opinion on latency should be excluded.

Dr. Kurman opines that the chronic inflammation associated with diseases like ulcerative colitis is irrelevant to the inflammation associated with exposure to a foreign body like talc.⁸¹ He criticizes Dr. Kane for not distinguishing between two, further proclaiming that the studies cited by Dr. Kane to show the impact of chronic inflammation are irrelevant here.⁸² Dr. Kurman states that there are differences

⁷⁹ *Id.* at 16.

⁸⁰ *Id.*

⁸¹ *Id.* at 18.

⁸² *Id.*

between the two types of inflammation, but he fails to give any basis for how those differences affect the propensity of each type of inflammation to lead (or not lead) to cancer development and why peer-reviewed studies of chronic inflammation should be disregarded in this matter. Instead, Dr. Kurman tells us that the differences in the types of inflammation matter in cancer development but he does not tell us why or how he came to that conclusion. There is no methodology and no literature cited to support his position, resulting in *ipse dixit* that should be excluded.

3. Detection of Talc in Ovarian Tissue

Dr. Kurman offers opinions that the detection of talc in ovarian tissue samples is not consistent with causation, is contrary to current data and cancer pathology, and that Dr. Kane uses a flawed methodology in arriving at her opinion (without actually identifying any flaw in her method). These opinions should be excluded as improper *ipse dixit*.

Dr. Kurman offers a critique of Dr. Kane's opinion that the detection of talc in pathology samples of ovarian tissue is consistent with causation, stating broadly that her conclusion is "unsupported by, and contrary to, the current data and understanding of ovarian cancer pathology."⁸³ Yet again, Dr. Kurman's opinion is nothing more than *ipse dixit* because it does not offer data, or medical literature

⁸³ *Id.* at 12.

citation to refute Dr. Kane's opinions, and he does not set forth any facts or data to show that finding talc in the tumor is inconsistent with causation.⁸⁴ Dr. Kurman next states that Dr. Kane used a flawed methodology because she identifies microscopy techniques that are not routinely used to examine ovarian tumors (unless there is a clear indication for using them) and because one of the studies Dr. Kane cites in her Report is a case report of a patient.⁸⁵ Dr. Kurman does not indicate why either of these are inconsistent with a methodology which considers the entire body of scientific evidence, instead giving *ipse dixit* criticism of two discrete pieces of Dr. Kane's larger scientific approach. This opinion should therefore be excluded.

Dr. Kurman also states that Dr. Kane's methodology is flawed because "the presence of talc particles in ovarian cancer tissue does not prove that the talc plays a causal role in the development of ovarian cancer."⁸⁶ This opinion does not pertain to methodology but is rather a difference of opinion (and a disagreement with an opinion that was never offered by Dr. Kane). Dr. Kurman's opinion should be excluded because it misstates Dr. Kane's opinion, and therefore is irrelevant, misleading, and not helpful to the jury (Dr. Kane never states that the presence of talc in the tissue itself proves that talc causes ovarian cancer).

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.* at 20.

Dr. Kurman's opinion is also excludable as *ipse dixit*. He describes an unrelated example to prove his point—that of the herpes simplex virus and cervical cancer. He does not address Dr. Kane's actual conclusion—that the presence of talc in ovarian tissue is "consistent with causation and provides additional evidence in support of a causal relationship." Dr. Kurman does not say how a proper methodology would interpret the evidence of talc in ovarian tissue and he does not say how the presence of talc in ovarian tissue is otherwise inconsistent with causation. Dr. Kurman complains of a discussion that is "methodologically flawed" without analysis or explanation. Such *ipse dixit* should be excluded.

4. Migration of Talc to the Ovaries

Dr. Kurman states that migration through the genital tract is not sufficiently supported in Dr. Kane's report, that the studies Dr. Kane cites do not support her conclusion, that the inhalation and lymphatic transport of talc would naturally mean that women who use perineal talc would also have talc-induced pulmonary disease, and that Dr. Kane's opinions are invalidated or undermined if ovarian cancer originates in the fallopian tubes. Each of these opinions critical of Dr. Kane's opinion on the migration of talc to the ovaries lacks any basis other than the *ipse dixit* opinions of Dr. Kurman.

Dr. Kurman critiques Dr. Kane’s statement “that migration through the genital tract to the ovaries is well established” for citing to “only two studies” in support.⁸⁷ While this criticism ignores the larger point that migration is widely accepted in the medical community (and which he readily notes in his own textbook discussed *infra*),⁸⁸ Dr. Kurman also offers no scientific foundation for his position that the studies cited by Dr. Kane do not provide support for her opinion. Dr. Kurman further criticizes the studies cited by Dr. Kane for being too far removed from the type of exposure involved in this litigation, deeming them “highly artificial,” but bases his opinion on studies investigating talc migration in monkeys, rats, and mice.⁸⁹ He gives some context for the two animal studies he cites, Wehner 1985 and Boorman 1995, but does not explain why they are more reliable than the two human studies cited by Dr. Kane. This is especially remarkable considering Dr. Kurman’s remarks from two pages earlier in his Report, asserting that “animal models [...] are of questionable value in understanding ovarian carcinogenesis in humans.”⁹⁰ Despite Dr. Kurman’s criticism of Dr. Kane for having relied on “only two studies” to

⁸⁷ *Id.* at 21.

⁸⁸ For example, the Federal Food and Drug Administration has acknowledged that “the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable.” [April 1, 2014 FDA Response to Dr. Epstein’s Citizen Petitions, attached hereto as **Exhibit L**.]

⁸⁹ Exhibit A, Kurman Report at 21-22.

⁹⁰ *Id.* at 19.

support a widely accepted conclusion, Dr. Kurman uses only one study to support his position that “even when particles are placed into the vagina, passage to the ovaries is quite unusual.”⁹¹ The study, which used India ink and not talcum powder, was relied upon by Dr. Kurman without analysis or explanation of why it should be given more weight than the literature cited by Dr. Kane, or why it is valid whereas the literature cited by Dr. Kane is not.

Dr. Kurman’s attempt to bolster his critique of the studies on which Dr. Kane relied to support her vulva-reproductive tract migration opinion relies only on speculation. Specifically, Dr. Kurman speculated that “the studies that Dr. Kane cites as finding talc in ovarian tissue do not support her contention that talc migrated there from the vulva through the reproductive tract.”⁹² Dr. Kurman’s only support for this conclusion is that the “presence of talc in ovarian tissues can be easily explained as a contaminant.”⁹³

Without citing to medical literature or offering any methodology to support his opinion, Dr. Kurman pronounces the ubiquity of everyday products and describes paper towels as “a very likely source of talc that can be introduced into tissues.”⁹⁴

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

He does not explain why such an occurrence is a more scientifically viable explanation for the presence of talc in ovarian tissue than that proffered by Dr. Kane and the literature she cites.

Furthermore, in attempting to legitimize his argument with the Heller, *et al.* study, Dr. Kurman credits an explanation to Heller's results that ignores all other possible explanations. This one explanation regarding contamination not only is most convenient to his position in this litigation but is also provided without any basis other than *ipse dixit*.⁹⁵ Dr. Kurman further does not cite, as he claims not to have read, a published paper that directly addresses and refutes his point about contamination.⁹⁶

In contesting the secondary route of talc migration identified by Dr. Kane as biologically plausible, inhalation and transport through the lymphatic system to the ovaries, Dr. Kurman offers no support in his report for why this is not biologically plausible. With no cited medical literature support, Dr. Kurman claims that "[i]f inhalation of talc were a significant route of exposure to ovarian tissue, one would expect to see evidence of talc-induced pulmonary disease in women who use perineal talc."⁹⁷ This, too, is *ipse dixit*.

⁹⁵ *Id.* at 23.

⁹⁶ See Exhibit H McDonald, et al., *supra*.

⁹⁷ Exhibit A, Kurman Report at 22.

Dr. Kurman offers no basis to support his opinion that inhaled talc would be expected to but does not cause pulmonary disease. Dr. Kurman also cherry-picks his points, on one hand, suggesting in this section of his report that talc should have the same effects on other organs and, on the other hand, testifying at his deposition that, while chronic inflammation can cause cancers to other organs and tissue, it does not cause ovarian cancer. Exhibit B, Kurman Dep. at 54:3-9; 61:20-23. By failing to analyze or even acknowledge potential differences between the development of pulmonary diseases and that of ovarian cancers, Dr. Kurman relies on a gap in logic to draw the comparison instead of providing a scientific basis or reliable methodology. Further, while Dr. Kurman might be “[un]aware of any such reports,” he has not described any methodology he used to locate or investigate relevant studies.⁹⁸

Dr. Kurman also seems willing to entirely disregard the two studies he referenced in the same paragraph, Suzuki and Marchiori, which found pulmonary complications associated with inhaled talc.⁹⁹ By making claims without scientific foundation and ignoring the science that already exists, Dr. Kurman offers opinions on inhalation and lymphatic transfer that amount only to unsubstantiated *ipse dixit*.

⁹⁸ *Id.* at 23.

⁹⁹ *Id.* at 22.

Dr. Kurman pronounces that “evidence that serous ovarian cancer originates in the fallopian tubes invalidates many of Dr. Kane’s more specific opinions...”¹⁰⁰ Disregarding Dr. Kane’s conclusion that proximal migration of talc is possible to either the ovaries or the fallopian tubes, Dr. Kurman expects the Court and juries to take his word for it that Dr. Kane’s conclusion is no longer valid if ovarian cancer originates in the fallopian tubes. Again, he offers no medical literature, citations, sources, analysis, or methodology to support or explain his opinion. Dr. Kurman takes the same approach in stating that fallopian tube origination of ovarian cancer undermines Dr. Kane’s opinion that tubal ligation impedes the proximal migration of talc. The only support Dr. Kurman provides here is to argue that tubal ligations are generally helpful to protect against ovarian cancer for other unrelated reasons. This is merely a distraction, doing nothing to explain the basis for Dr. Kurman’s position that tubal ligations cannot also impede the proximal migration of talc, and contradicts his own previous statements in his textbook (discussed *infra*). This opinion should be excluded as *ipse dixit*.

One final example of Dr. Kurman’s use of his subjective scientific standard is on the very important topic of talc-induced chronic inflammation, the very cornerstone of talc-induced oncogenesis. In short, Dr. Kurman opined that gynecologic tissue generally, and ovarian epithelial cells specifically, would react to

¹⁰⁰ *Id.* at 23.

talc exposure by eliciting a foreign-body granulomatous response. Yet, Dr. Kurman offers absolutely no scientific support for this opinion. In fact, he eventually acknowledged that there is not a single study that confirms the presence of talc particles or fibers in gynecologic tissue, *and* evidences a foreign-body granulomatous response.¹⁰¹ His entire basis for disagreeing with the notion that talc can migrate from the perineum to the ovaries and sometimes cause ovarian cancer is his speculative, personal opinion that, if talc could reach the ovaries, he assumes it would elicit an inflammatory foreign-body granulomatous reaction, and he would have seen it before, and he hasn't.¹⁰²

At the same time Dr. Kurman acknowledges the opposite, without explaining the contradiction, that there are studies evidencing the presence of talc in ovarian tissue, with absolutely no evidence of a foreign-body granulomatous response.¹⁰³

Dr. Kurman testified in his deposition that giant cell granulomatous inflammation is “very, very rare(ly)” observed in gynecologic tissue. *Id.* at 52:5-9. He further opines that the notion that talc exposure can cause chronic inflammation, which can cause ovarian cancer, is not biologically plausible because, “I have never

¹⁰¹ Exhibit B, Kurman Dep. at 275:1-6.

¹⁰² *Id.* at 24:2-8.

¹⁰³ *Id.* at 274:6-13.

seen that, in all my experience in ovarian cancer, foreign body giant cell reaction.”¹⁰⁴

Dr. Kurman’s repeated causation analysis of “because I’ve never seen it, it cannot be so” is in no way scientific, and does not comport with the law on admissible scientific opinions.

IV. CONCLUSION

For this and the other foregoing reasons, the Court should grant Plaintiffs’ *Daubert* motion to exclude the opinions of Robert Kurman, M.D.

Dated: May 7, 2019

Respectfully submitted,

/s/ Michelle A. Parfitt

Michelle A. Parfitt

ASHCRAFT & GEREL, LLP

1825 K Street, NW, Suite 700

Washington, DC 20006

Tel: 202-783-6400

Fax: 202-416-6392

mparfitt@ashcraftlaw.com

¹⁰⁴ *Id.* at 58:5-6. (Emphasis added) and 59:11-60:12, “Q: Again, you said you’ve never seen, in your career, a chronic inflammatory response to talc like giant cell granulomas in gynecologic tissue; is that what you are saying? A. That’s correct. Q. So my question is, you’re saying it’s not biologically plausible because you’ve never seen it; right? A. I haven’t seen that type of reaction in association with ovarian cancer during my entire career.”

/s/ P. Leigh O'Dell

P. Leigh O'Dell

BEASLEY, ALLEN, CROW, METHVIN,
PORTIS & MILES, P.C.

218 Commerce Street

Montgomery, AL 36104

Tel: 334-269-2343

Fax: 334-954-7555

Leigh.odell@beasleyallen.com

Plaintiffs' Co-Lead Counsel

/s/ Christopher M. Placitella

Christopher M. Placitella

COHEN, PLACITELLA & ROTH, P.C.

127 Maple Avenue

Red Bank, NJ 07701

Tel: 732-747-9003

Fax: 732-747-9004

cplacitella@cprlaw.com

Plaintiffs' Liaison Counsel

PLAINTIFFS' EXECUTIVE COMMITTEE:

Warren T. Burns

BURNS CHAREST LLP

500 North Akard Street, Suite 2810

Dallas, TX 75201

Tel: 469-904-4551

Fax: 469-444-5002

wburns@burnscharest.com

Richard Golomb

GOLOMB & HONIK, P.C.

1515 Market Street, Suite 1100

Philadelphia, PA 19102

Tel: 215-985-9177

rgolomb@golombhonik.com

Richard H. Meadow

THE LANIER LAW FIRM PC

6810 FM 1960 West

Houston, TX 77069

Tel: 713-659-5200

Fax: 713-659-2204

richard.meadow@lanierlawfirm.com

Hunter J. Shkolnik

NAPOLI SHKOLNIK PLLC

360 Lexington Avenue, 11th Floor

New York, NY 10017

Tel: 212-397-1000

hunter@napolilaw.com

PLAINTIFFS' STEERING COMMITTEE:

Laurence S. Berman
LEVIN, SEDRAN & BERMAN LLP
510 Walnut Street, Suite 500
Philadelphia, PA 19106
Tel: 215-592-1500
Fax: 215-592-4663
lberman@lfsblaw.com

Timothy G. Blood
BLOOD, HURST & O'REARDON,
LLP
701 B Street, Suite 1700
San Diego, CA 92101
Tel: 619-338-1100
Fax: 619-338-1101
tblood@bholaw.com

Sindhu S. Daniel
BARON & BUDD, P.C.
3102 Oak Lawn Avenue, #1100
Dallas, TX 75219
Tel: 214-521-3605
Fax: 214-520-1181
sdaniel@baronbudd.com

Jeff S. Gibson
WAGNER REESE, LLP
11939 N. Meridian St.
Carmel, IN 46032
Tel: (317) 569-0000
Fax: (317) 569-8088
jgibson@wagnerreese.com

Kristie M. Hightower
LUNDY, LUNDY, SOILEAU & SOUTH,
LLP
501 Broad Street
Lake Charles, LA 70601
Tel: 337-439-0707
Fax: 337-439-1029
khightower@lundylawllp.com

Daniel R. Lapinski
MOTLEY RICE LLC
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
Tel: 856-667-0500
Fax: 856-667-5133
dlapinski@motleyrice.com

Victoria Maniatis
SANDERS PHILLIPS GROSSMAN, LLC
100 Garden City Plaza, Suite 500
Garden City, NJ 11530
Tel: 516-640-3913
Fax: 516-741-0128
vmaniatis@thesandersfirm.com

Carmen S. Scott
MOTLEY RICE LLC
28 Bridgeside Boulevard
Mount Pleasant, SC 29464
Tel: 843-216-9162
Fax: 843-216-9450
cscott@motleyrice.com

Eric H. Weinberg
THE WEINBERG LAW FIRM
149 Livingston Avenue
New Brunswick, NJ 08901
Tel: 732-246-7080
Fax: 732-246-1981
ehw@erichweinberg.com

Richard L. Root
MORRIS BART, LLC
Pan America Life Center
601 Poydras St., 24th Fl.
New Orleans, LA 70130
Tel. 504-525-8000
Fax: 504-599-3392
rroot@morrisbart.com

Christopher V. Tisi
LEVIN PAPANTONIO
316 South Baylen St.
Pensacola, FL 32502
(850) 435-7000
ctisi@levinlaw.com